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Appl. Serial No. 10/526,744
Atty. Dkt. No. 053466-0395

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Noboru MAKI et al.
Title: HBV PRECORE PROTEIN HAVING A
PARTICLE-FORMING ABILITY
Appl. No.: 10/526,744
Filing Date: 03/07/2005
Examiner: Unassigned
Art Unit: Unassigned

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INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

All documents listed on the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding International application. Copies of the documents are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and JPO. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner. An English-language abstract of the foreign-language document has been provided.


Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 25, 2005

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5571
Facsimile: (202) 672-5399

By 
for *Matthew Mulkeen*
Harold C. Wegner *Reg. No. 44,250*
Attorney for Applicant
Registration No. 25,258

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| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: March 25, 2005 <i>(use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/526,744 |
| | | | | Filing Date | 03/07/2005 |
| | | | | First Named Inventor | Noboru MAKI |
| | | | | Group Art Unit | Unassigned |
| | | | | Examiner Name | Unassigned |
| | | | | Attorney Docket Number | 053466-0395 |
| Sheet | 1 | of | 1 | | |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|----------------------|-----------------------------------|---|---|---|
| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|--|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | A1 | PCT | WO 01/40279 | A2 | Innogenetics N.V. | 06/07/2001 | | |
| | A2 | PCT | WO 02/14871 | A1 | Advanced Life Science Institute, Inc. | 02/21/2002 | | Abs |
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| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ⁶ |
| | A3 | KIMURA, Tatsuji et al., "Sensitive Enzyme Immunoassay for Hepatitis B Virus Core-Related Antigens and Their Correlation to Virus Load", <i>Journal of Clinical Microbiology</i> , February 2002, Vol. 40, No. 2, pgs. 439-435. | | |
| | A4 | SAKAMOTO, Y. et al., "Full and Empty Particles of Hepatitis B Virus in Hepatocytes from Patients with HBsAg – Positive Chronic Active Hepatitis", <i>Laboratory Investigation</i> , 1983, Vol. 48, No. 6, pgs. 678-682. | | |
| | A5 | TAKAHASHI, K. et al., "Molecular Heterogeneity of e Antigen Polypeptides in Sera From Carriers of Hepatitis B Virus", <i>The Journal of Immunology</i> , November 1991, Vol. 147, no. 9, pgs. 3156-3160. | | |
| | A6 | TERRE, S., et al., "Defective Hepatitis B Virus Particles Are Generated by Packaging and Reverse Transcription of Spliced Viral RNAs In Vivo", <i>Journal of Virology</i> , October 1991, Vol. 65, No. 10, pgs. 5539-5543. | | |
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|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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